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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,898	11/28/2000	Leroy Hood	066661-0021	7808
41552 7590 12/10/2007 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			EXAMINER ZEMAN, MARY K	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/724,898

Applicant(s)

HOOD ET AL.

Examiner

Mary K. Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-11,13,15,16,65,70-80,90,95-104,138,139,141 and 143-189 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-11,13,15,16,65,70-80,90,95-104,138,139,141 and 143-189 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/10/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/07 has been entered.

Claims 1, 6-11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141, 143-189 are pending in this application. all other claims have been canceled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1,6-9, 11, 13, 15-16,65,70-80,90,95-104, 138-139, 141, and 143-189 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained.

The claims have been amended to recite an output step, however, the data which is output by the output step does not meet the standard of being concrete, tangible and useful. The output of the non-specific multidimensional coordinate point in multidimensional space is not a concrete, tangible and useful result. It requires further interpretation to be meaningful and

useful. The systems, carrier waves, and media for carrying out the same methods are non-statutory as they carry out and/or contain non-statutory methods.

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (“application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”); *Benson*, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it “has no substantial practical application”).

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

- 1) The claimed invention “transforms” an article or physical object to a different state or thing.
- 2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” *AT&T*, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and *Fisher*, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also *Corning*, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is

“abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

See also: 1300 OG 142, 11/22/2005.

Claims 1,6-9, 11, 13, 15-16,65,70-80,90,95-104, 138-139, 141, and 143-189 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

Claim 1 is directed to a method of determining a comparative expression profile in an individual comprising creating a multidimensional space related to expression levels of molecules, determining a multidimensional point for reference and test individuals, determining a health-associated region for the reference individuals, comparing a multidimensional coordinate point of the individual to the health-associated region of the reference population, and determining whether the multidimensional coordinate point of the individual is outside of the health-associated region which indicates a perturbed expression profile. Claims 90 and 144 are directed to a method of diagnosing a health states in an individual comprising similar steps. The specification on pages 1 and 3 discloses that the instant invention is useful for predictive medicine and efficiently diagnosing a disease based on a gene expression pattern in an individual. However the disclosed utility is not applicable to the instant claims. For example, the claimed methods "determine" whether an expression profile of an individual is "perturbed" from the comparison to a profile to the "health-associated" reference population. Neither the specification, not the claims disclose any information about "health-associated" reference

individuals and/or what the "health-associated" reference indicates, e.g., reference individuals are healthy, carry disease markers, carry markers specific for a particular stage of a disease, carry markers for specific alleles, carry ancestral markers, etc. Determining that an individual has a "perturbed" profile without knowing what a reference represents does not provide any information about a disease stage or health conditions of the individual, and therefore does not allow one skilled in the art to "effectively diagnose a disease." Thus, the claimed method does not have a "result" which is "of immediate benefit" because one skilled in the art would not know what "perturbed" profile indicates. Consequently, the instant claims do not have substantial utility (a "real world" use) because the methods do not have a stated correlation between, for example, a disease and a determined perturbation and is not particular to a specific health condition. Therefore, determining what a "perturbed" expression profile indicates would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. The instant invention also does not have a specific utility, because absent any disclosure about, for example, a stage of health or disease and/or allelic markers in a affected and unaffected population, and whether the "reference profile" represents a healthy or diseased, or specific subpopulation, etc. (i.e., absent some correlation between a specific population and disease to be diagnosed), the asserted utility is not specific. No such information is recited in the instant claims and further research would be required to determine such a correlation. Applicant is reminded that a "use" to perform further research is not a utility under 35 U.S.C. 101.

Claims 138-139, 141, and 143 are directed to a computer system and a computer readable medium performing steps of the instant methods. Because the method does not have a

specific, substantial and credible utility for the reasons set forth above, any computer system and/or program implementing such a method also lacks utility. The system and a computer readable medium in this case perform a method which produces no useful result, and one of ordinary skill in the art would not know for what purpose or to what useful end such a system might be used for, therefore, the invention lacks utility.

For the reasons stated above claims 1,6-9, 11, 13, 15-16,65,70-80,90,95-104, 138-139, 141, and 143-189 lack patentable utility under 35 U.S.C. 101.

Claims 1,6-9, 11, 13, 15-16,65,70-80,90, 95-104, 138-139, 141, and 143-189 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The above rejections are reiterated from the prior Office action. Applicants' arguments have been fully considered, but they are not found persuasive.

Despite applicants' assertions, the claimed invention lacks patentable utility because it lacks specific and substantial utility. While applicants point to possible uses for their claimed invention, all such uses (e.g. a "health state") are general - applicants fail to point out a single specific (e.g. a single disease, condition, etc.) use for which one could readily apply applicants' claimed invention. Furthermore, given the generality of the claimed method, it is not of immediate benefit because one would have no idea of what molecules (genes, proteins, metabolites, etc.) to test for a given "health-state" unless they were to carry out considerable

research to identify those molecules. As applicants themselves point out, a "reference profile" could be either healthy or diseased (remarks, page 18, third paragraph). Therefore, one of skill in the art would not know what a perturbed profile indicates as it could indicate either the presence or absence of disease.

As argued above, since the methods have no specific, substantial, and credible utility, neither do the computer, computer readable media, and carrier waves that employ the method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Mary K. Zeman/